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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,215	03/09/2004	Scott T. Moore	10000-353	2716

7590 10/10/2007

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,215	MOORE ET AL.	
	Examiner	Art Unit	
	Amy T. Lang	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claims 1, 11, 23, and 35** are objected to because of the following informalities: Claims 1, 11, 23, and 35 all recite the soft pusher member positioned "at the acute bend in the body during deployment of the preloaded stent." It is the examiner's position it appears that the Applicant is claiming a body part. Applicant is recommended to amend the claims to recite wherein the soft pusher member is *adapted* to be positioned at an acute bend in the body during deployment of the preloaded stent. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 23** recites the limitation "the acute bend" in line 22 of the claim. There is insufficient antecedent basis for this limitation in the claim.

4. **Claim 15** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites wherein the pusher member has a diameter equal to or greater than the "preloaded stent while the stent is loaded in the introducer catheter."

Therefore, it is the examiner's position that it is unclear as to whether the diameter of the stent is being compared in a preloaded state or after it loaded within the catheter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US 6,425,898) in view of Ravenscroft (US 5,702,418).

With regard to **claims 1, 3-5, 7, 8, 11, 13, 14, 17, 19, and 20**, Wilson discloses a stent delivery system comprising a pusher assembly (see entire document). As shown in Figure 5, the stent delivery system includes a shaft (10) having a first tubular portion (16) and a second tubular portion (18) disposed within outer sheath (40) (column 5, lines 18-28). The stent delivery system is utilized in such vessels as the carotid artery so that the outer diameter of the shaft is predetermined (column 1, lines 58-61). The

second tubular portion (18) extends distally from the fist tubular portion (16) and is comprised of a metal reinforced polymer material including braided polyimide tubing (column 5, lines 27-35; Figure 5). Therefore, the second tubular portion comprises a flexible section (between members 17 and 22) proximal of the stent carrying section (between members 22 and 34).

Pusher member (22) is configured to urge a stent from the stent delivery system (column 5, line 59 through column 6, line 5). As shown in Figure 5, the pusher member (22) is disposed along the second tubular portion (18) proximal of the stent carrying section. Wilson teaches that the pusher member is made from a radiopaque polymer and cooperates with the preloaded stent (column 5, lines 58-67).

Shaft (10) is disposed within the inner passageway provided by sheath (40) (column 5, lines 18-20). Therefore, the outer diameter of the first tubular portion is less than the inside diameter of sheath/catheter (40). Wilson teaches that the sheath constrains the stent so that first tubular portion effectively occupies the inside diameter of sheath (40) (column 6, lines 31-33).

Wilson discloses that the first tubular member may be made from any suitable material know to those of ordinary skill in the art, but does not specifically disclose a non-rigid polymer (column 5, lines 23-27).

Ravenscroft teaches a similar stent delivery system comprising a first tubular portion (15), a second tubular portion (16 and 17) and a pusher member (23) (Figure 5, column 5, lines 3-53). The first tubular portion (15) is further disclosed as a plastic material such as PEBAX®, which clearly overlaps the instantly claimed non-rigid

polymer (column 5, lines 23-30). Since Ravenscroft discloses a similar device with a first tubular portion comprised of a non-rigid polymer and Wilson is open to the material of the first tubular member, it would have been obvious to one of ordinary skill at the time of the invention for the first tubular member of Wilson to be comprised of a non-rigid polymer. Therefore, the first tubular portion comprised of PEBAX® and effectively occupying the inside diameter of the sheath would provide sufficient rigidity and support for pushing the stent through the catheter and reduce the likelihood and severity of kinking.

Wilson does not specifically disclose the pusher member as comprising polytetrafluoroethylene or a low density polymer.

Wilson teaches that the pusher member (22) may be made from any material known in the art and specifically discloses a polymer (column 5, lines 58-63). Since polytetrafluoroethylene and low density polymers are well known in the art and Wilson is open to any suitable polymer, it would have been obvious at the time of the location for Wilson to utilize a polytetrafluoroethylene or a low density polymer.

With regard to **claims 2 and 35**, since the stent delivery system of Wilson in view of Ravenscroft overlaps the instant claims, it would also display the same kink characteristics as instantly claimed.

With regard to **claims 6 and 18**, as shown in Figure 5 of Wilson, the second tubular portion (18) has a smaller outer diameter than the first tubular portion.

With regard to **claims 9 and 21**, Wilson teaches that the second tubular portion may also be comprised of Nitinol (column 5, line 32).

With regard to **claims 10, 12, and 22**, as shown in Figure 5 of Wilson, the distal end of the second tubular portion is affixed to tapered distal tip (20). The stent carrying section and flexible section of member (18) are a continuous element (Figure 5).

With regard to **claim 15**, as shown in Figure 2 of Wilson, pusher member (22) has an outer diameter equal to the stent when the stent is loaded in the sheath/catheter (40).

With regard to **claim 16**, the stent is disclosed as comprised of Nitinol, which overlaps the instantly claimed self-expanding (column 2, lines 16-19).

With regard to **claim 23-28**, Wilson further discloses joint (17) attaching the first and second tubular portions through bonding or heat fusing so that one integral piece is formed (column 5, lines 35-38).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kugler (US 6,790,222 B2) teaches that polytetrafluoroethylene and low density polymers are well known in the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-277-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/5/2007
AL

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/6/07